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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/571,146	MORTON ET AL.	
	Examiner	Art Unit	
	JAMES H. ALSTRUM ACEVEDO	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24, 27-33, and 35-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24, 27-33, and 35-42* is/are rejected.

7)☒ Claim(s) *18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24, 27-33, and 35-42 are pending. Applicants' previously cancelled claims 25-26 and 34. Applicants amended claim 1. Receipt and consideration of Applicants' amended claim set and remarks/arguments submitted on July 29, 2010 are acknowledged.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Specification

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Dependent claim 18 depends from dependent claim 16, which claims a pharmaceutical composition comprising composite active particles in accordance with the claimed method of claim 1. The composite particles present in the claimed composition of claim 16 have a coating of additive material on the surface of the active particles, per Applicants'

amendment to claim 1. As a result, dependent claim 18 no longer further limits dependent claim 16, because it recites a limitation that has been incorporated into parent independent claim 1.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 16-24, 27, 29-32, 35, and 41-42 remain rejected under 35 U.S.C. 102(b) as being anticipated by Curtet et al. (U.S. Patent No. 4,895,726) (IDS reference).

Applicants claim (1) a method of making composite particles comprising jet milling active particles in the presence of additive particles and (2) a pharmaceutical composition comprising the products made by (1), wherein the additive material coats the active particles.

In Preparation I, Curtet discloses the preparation of **a pharmaceutical composition comprising (i) fenofibrate (i.e. an active agent) and (ii) sodium lauryl sulfate (i.e. an additive material) by co-micronizing (i) and (ii) with an air-jet micronizer (i.e. a jet mill) to obtain a powder with a median particle size of three microns** (col. 2, lines 26-42). After the first step disclosed in Curtet's preparation, Curtet has reduced to practice Applicants' claimed method. Suitable surfactants are solids (col. 1, lines 52-53).

Curtet teaches that the co-micronization of fenofibrate and solid surfactant leads to improved dissolution of the active principle and bio-availability (col. 1, lines 28-43 and 52-56). **the powder obtained has a mean particle size of less than 15 microns, particularly preferably less than 5 microns** (col. 1, lines 61-66). Regarding the recitation of the additive material forming a coating on the active material and the recited FPF(ED) and FPF(MD) properties, because Curtet's method utilizes the same required steps and materials recited in

Applicants' method, Curtet's composition after the first step, must exhibit the same properties. Regarding claim 35, because Curtet does not state that the air-jet milling was performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling was done in the presence of air. Thus, Applicants' claims are properly anticipated by Curtet's teachings.

Response to Arguments

Applicant's arguments filed July 29, 2010 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by arguing that Curtet's exemplified process of co-jet milling fenofibrate with SLS surfactant to yield particles having a median size of three microns allegedly is not anticipatory, because (1) Curtet does not state an intention to administer the formulations pulmonarily, but rather to treat hyperlipidemia and hypercholesterolemia; (2) Curtet's teachings are focused on oral formulations; (3) allegedly Curtet does not disclose particles suitable for pulmonary administration; (4) allegedly Curtet's method does not result in a coating of surfactant onto fenofibrate particles, because in Applicants' opinion this would contravene Curtet's intention to improve drug bio-availability; (5) the actives disclosed in Curtet's specification are allegedly not suitable for pulmonary administration, in part because Curtet teaches dosage amounts much greater than are contemplated in Applicants' specification; and (6) Applicants use an additive for a different purpose (i.e. increase FPF) than the purpose for which Curtet utilizes surfactant additive (i.e. increase bio-availability).

The Examiner respectfully disagrees with Applicants' traversal arguments. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., specific drugs or drug classes,

specific dosage amounts, and specific additives) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's argument (1)-(3) and (6), the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). More specifically regarding (3), Curtet's particles have a size that is suitable form pulmonary administration, a fact Applicants do not dispute. Curtet teaches the same required process step as recited in Applicants' claims. Applicants' claims do not recite any specific kinds of active agents, additive materials, or dosage amounts. Thus, Curtet's teachings properly anticipate the claimed method. Regarding (4), this argument is unpersuasive because it represents mere attorney argument and speculation, unsupported by any objective evidence. Regarding (5), this argument fails to address the merits of the instant rejection based upon the process exemplified by Curtet. Applicants' arguments are unpersuasive for the reasons stated above and the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7-12, 16-24, 27, 29-32, 35-36, and 39-42 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Curtet et al. (U.S. Patent No. 4,895,726) (IDS reference).

Applicant Claims

Applicants claim a method and composition as described above, wherein the method may be practiced at different temperatures and pressures and the MMAD of the resulting particles is not more than 1 micron.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Curtet are set forth above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Curtet is silent regarding the temperature and pressure used in the disclosed jet-milling and teaches an overlapping range of particle size (i.e. less than 5 microns). Curtet's teachings render the claims obvious, as explained below.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill at the time of the instant invention to vary the temperature and pressure utilized during the jet milling, because varying temperature and pressure is a routine modification of processes in the art. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during Curtet's jet milling process and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process, absent evidence of the criticality of the temperature and pressure recited in Applicants' claims. Regarding the overlapping particle size, a prima facie case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Applicants' data is noted. Applicants' data is not commensurate in scope with Applicants' claims (i.e. it is limited to the combination of specific active agents [i.e. apomorphine and clobozam] with specific additive materials [i.e. magnesium stearate, lecithin, or L-leucine]). Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments filed July 29, 2010 have been fully considered but they are not persuasive. Applicants traverse the instant rejection by reiterating the arguments traversing the first rejection based on Curtet. The Office's rebuttal of Applicants' arguments is herein incorporated by reference and the rejection is maintained.

Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Curtet et al. (U.S. Patent No. 4,895,726) (IDS reference) as applied to claims 1, 7-12, 16-24, 27, 29-32, 35-36, and 39-42 above, and further in view of Hochschild (U.S. Patent No. 4,374,082).

Applicant Claims

Applicants claim a method and composition as described above, wherein the additive is lecithin (i.e. a phospholipid).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Curtet are set forth above.

Hochschild teaches **that lecithin is a solid** that **is well known as an emulsifier** used in food products (col. 1, lines 13-15 and 22-26). The term emulsifier reads on surfactant.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Curtet lacks the teaching of a method utilizing lecithin as a co-jet milled additive. This deficiency is cured by teachings of Hochschild.

Finding of Prima Facie Obviousness Rationale and Motivation (MPEP §2142-2143)

It would have been *prima facie* obvious to a person of ordinary skill at the time of the instant invention to modify Curtet's exemplified process and utilize lecithin in lieu of or in addition to SLS (i.e. sodium lauryl sulfate), because Curtet teaches that suitable surfactants are solid surfactants (Curtet: col. 1, lines 52-53). An ordinary skilled artisan would have been motivated to utilize lecithin, because it is a well-known solid surfactant and would be considered suitable for use in pharmaceutical formulations, as evidenced by the fact that Hochschild teaches that it is a well-known emulsifier in the food arts. An ordinary skilled artisan would have had a reasonable expectation of successfully modifying the teachings of Curtet to utilize lecithin as the surfactant or in addition to SLS, because Curtet teaches that suitable surfactants are solids and lecithin is a well-known solid surfactant. Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because the combined teachings of the prior art is fairly suggestive of the claimed invention.

Response to Arguments

Applicant's arguments with respect to claims 2 and 6 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-8, 11-12, 16-20, 23-24, 27, and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 16-19 and 21-22 of U.S. Patent No. 7,736,670 (U.S. Patent No. '670) (USPN '670).[1] Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 1 of USPN '670 claims a method of making composite particles for use in a pharmaceutical composition for pulmonary administration comprising a

milling step in which particles of active material are milled in the presence of particles of additive material, wherein the milling comprises one of three possibilities, including jet milling, and the additive material is dispersed over the active material (i.e. coated).

The primary difference between claim 1 of the instant application and claim 1 of USPN '670, is that USPN '670 recites different alternative milling procedures and recites that agglomerates of the particles of active and additive material are both broken up. These differences nonetheless do not distinguish the claims of the instant application from the claims of USPN '670; because the claims of the instant application recite the same co-jet milling step as is contemplated by the claims of USPN '670and would necessarily have the same or substantially similar result of breaking up agglomerates of active and/or additive particles. Regarding claim 35, because the claims of USPN '670 do not state that the jet milling is performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling is done in the presence of air.

Regarding the recitation of different temperatures or pressures in the claims of the instant application, varying the temperature and pressure utilized during jet milling would be a routine modification of the jet-milling processes of USPN '670, absent the demonstration of the criticality of a particular temperature and/or pressure range or value. Concerning overlapping particle size ranges, a prima facie case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during the jet milling process of USPN '670and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process

[1] This rejection was previously provisional and was based on Application No. 10/433,072, which has issued as a

Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1, 5-8, 11-12, 16-20, 23-24, 27, and 35 *prima facie* obvious over claims 1, 4, 16-19 and 21-22 of U.S. Patent No. 7,736,670 (U.S. Patent No. '670) (USPN '670).

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 1-2, 5-8, 11-12, 16-24, 27, 35-36, and 39-40 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 20, 33-35, 37, 39, 42-43, and 59-51 of copending Application No. 10/433,185 (copending '185). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 1 of copending '185 claims a method of preparing microparticles for use in a pharmaceutical composition for pulmonary administration comprising milling particles of active material are milled in the presence of particles of hydrophobic material (e.g. magnesium stearate or a phospholipid) material, wherein the milling comprises one of three possibilities, including jet milling, and the hydrophobic material is dispersed over the active material (i.e. coated).

U.S. patent.

The primary difference between claim 1 of the instant application and claim 1 of copending '185, is that copending '185 recites different alternative milling procedures and recites that agglomerates of the particles of both active and hydrophobic material are broken up, and the resulting microparticles exhibit delayed dissolution of the active substance. These differences nonetheless do not distinguish the claims of the instant application from the claims of copending '185; because the claims of the instant application recite the same co-jet milling step as is contemplated by the claims of copending '185 and would necessarily have the same or substantially similar result of breaking up agglomerates of active and/or additive particles. Regarding claim 35, because the claims of copending '185 do not state that the jet milling is performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling is done in the presence of air. Regarding the recitation of different temperatures or pressures in the claims of the instant application, varying the temperature and pressure utilized during jet milling would be a routine modification of the jet-milling processes of copending '185, absent the demonstration of the criticality of a particular temperature and/or pressure range or value. Concerning overlapping particle size ranges, a prima facie case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during the jet milling process of copending '185 and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-2, 5-8, 11-12, 16-24, 27, 35-36, and 39-40 *prima facie*

obvious over 20, 33-35, 37, 39, 42-43, and 59-51 of copending Application No. 10/433,185 (copending '185).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 1-2, 5, 7-8, 11-12, 16-17, 21-22, 27, 29-33, 35, and 41-42 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 9 of copending Application No. 10/552,326 (copending '326) (US filing date of March 9, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Dependent claim 9 of copending '326 claims a passive dry powder inhaler device comprising a dry powder formulation comprising (i) apomorphine and a metal stearate, wherein upon actuation of the device, a dosing efficiency at 5 microns of at least 70% is achieved, and wherein the composite active particles of the pharmaceutical composition are prepared by jet milling apomorphine particles (i.e. active

particles) in the presence of metal stearate additive material. Claim 9 of copending '326 anticipates claims 1-2, 5, 16, 29, and 33 of the instant application.

Regarding the remaining claims of the instant application, these claims are an obvious modification of claim 9 of copending '326 as articulated below. The differences between the remaining claims of the instant application and claim 9 of copending '326 is that copending '326 explicitly recites an overlapping particles size and/or dosing efficiency. Regarding claim 35, because the claim 9 of copending '326 does not state that the jet milling is performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling is done in the presence of air.

Regarding the recitation of different temperatures or pressures in the claims of the instant application, varying the temperature and pressure utilized during jet milling would be a routine modification of the jet-milling processes recited in claim 9 of copending '326, absent the demonstration of the criticality of a particular temperature and/or pressure range or value. Concerning overlapping particle size ranges, a prima facie case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during the jet milling process of copending '326 and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-2, 5, 2-8, 11-12, 16-17, 21-22, 27, 29-33, 35, and 41-42 *prima facie* obvious over claim 9 of copending Application No. 10/552,326 (copending '326).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 1, 7-8, 11-16, 28, and 35-38 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-9, and 26 of copending Application No. 11/791,385 (copending '385). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Dependent claim 26 of copending '385 claims a method of preparing a powder formulation wherein active particles are co-milled with an additive material, carrier particles are separately co-milled with an additive material and the co-milled active and carrier particles are combined, and wherein the milling is selected from ball milling, jet milling, or milling using a high pressure homogenizer, or combination thereof.

The primary difference between claim 1 of the instant application and claim 26 of copending '385, is that claim 26 of copending '385 recites different alternative milling procedures and specifies that carrier particles can be separately co-milled with additive material. These differences nonetheless do not distinguish the claims of the instant application from the claims of copending '385; because the claims of the instant application recite the same co-jet

milling step as is contemplated by the claims of copending '385. Regarding claim 35, because the claims of copending '385 do not state that the jet milling is performed *in vacuo* or under inert conditions it is reasonable to conclude that the milling is done in the presence of air. Regarding the recitation of different temperatures or pressures in the claims of the instant application, varying the temperature and pressure utilized during jet milling would be a routine modification of the jet-milling processes of copending '385, absent the demonstration of the criticality of a particular temperature and/or pressure range or value. Dependent claims 5-6 of copending '385, evidences that it would have been an obvious modification of the claimed method of copending '385 to utilize carrier particles having a median diameter between 3 microns and 40 microns and active particles with a diameter of less than 10 microns. These particle size ranges for carrier and active particles, respectively, overlap with the ranges recited in the dependent claims of the instant application. Concerning overlapping particle size ranges, a prima facie case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05. Thus an ordinary skilled artisan would have been motivated to experiment with the temperature and pressure utilized during the jet milling process of copending '385 and would have had an expectation of successfully modifying the temperature and pressure used in said jet milling process. Regarding claims 16 and 28, it is the Examiner's position that a method of making a powder formulation comprising particles of active, additive material, and carrier necessarily results in the preparation of a pharmaceutical composition. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1, 7-8, 11-16, 28, and 35 *prima facie* obvious over claims 1-3, 5-9, and 26 of copending Application No. 11/791,385 (copending '385).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants did not traverse this rejection and indicated they would consider the filing of a terminal disclaimer upon identification of allowable subject matter.

Claims 1-12, 16-24, 29-32, 35-36, and 39-42 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 4, 6, 12, 15-22, 26, 30, and 39-40 of copending Application No. 11/791,670 (copending '670). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 15 of copending '670 claims a method of preparing a pharmaceutical formulation comprising fusing an additive material (i.e. dispersing agent) to the surface of solid pharmaceutically active particles and admixing with a liquefied propellant gas.

Independent claim 15 of copending '670 does not explicitly recite jet-milling or that the dispersing agent coats the active agent particles. It is the Examiner's position that the fusing step is equivalent to milling, as evidenced by dependent claim 17 of copending'670, which recites that mechanical energy is applied to contact the dispersing agent and particles of active agent and

fuse these components together. Regarding the recitation that the additive particles coat the active particles, it is the Examiner's position that the fusing step of copending'670 necessarily coats the additive material onto the active particles, as evidenced, for example, by dependent claim 19 of copending '670, which explicitly states that the dispersing agent at least partially coats the active agent. It is the Examiner's position that the ordinary skilled artisan would readily recognize jet milling as a conventional technique used to obtain fine particulate compositions that necessarily utilizes the application of mechanical energy. Regarding the properties (e.g. FPF) recited in Applicants' dependent claims, it is the Examiner's position that these properties are necessarily present in the particulate formulations claimed or made by the claimed processes of copending '670. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 1-12, 16-24, 29-32, 35-36, and 39-42 *prima facie* obvious over claims 1, 4, 6, 12, 15-22, 26, 30, and 39-40 of copending Application No. 11/791,670 (copending '670).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-12, 16-24, 29-32, 35-36, and 39-42 have been considered but are moot in view of the new ground(s) of rejection.

Claims 16-18, 21-24, and 27-33 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 35, 38,

41-43, and 45 of copending Application No. 12/767,530 (copending '530).[2] Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of recited claims claim methods of making particles comprising co-jet milling particles of active material with particles of additive material and both claim sets claim pharmaceutical compositions produced by said method. Independent claim 1 of the instant application is described above. Independent claim 1 of copending '530 claims composite active particles for use in a pharmaceutical composition for pulmonary administration comprising particles of active material with particles of additive material on the surface of the active particles, wherein the composite particles have a MMAD of 10 microns or less.

The primary difference between independent claim 35 of copending '530 and the rejected composition claims of the instant application is that the claims of copending '530 do not recite that the additive material is present as a coating on the surface of the active particles. This difference is not material, because for the additive particles of the instant application to contain a coating of additive material that additive material must be on the surface of the active particles as is recited in the claims of copending '530. The dependent claims of copending '530 and the instant application recite the same or substantially similar limitations. Regarding particle size, the claims of copending '530 recite particle size ranges that overlap with the ranges recited in the rejected claims of the instant application. A *prima facie* case of obviousness necessarily exists when the prior art range overlaps or touches a claimed range, such as in the instant rejection. MPEP § 2144.05.

[2] Copending '530 was filed on March 17, 2010.

Regarding the recited properties (e.g. FPF) of the claimed compositions, it is the Examiner's position that these properties are necessarily present in the particulate formulations claimed in copending '530. Regarding dependent claim 33 of the instant application, it is a prima facie obvious modification of the claimed particles/compositions of copending '530 to place said particles/compositions into a dry powder inhaler, as evidenced by dependent claim 45 of copending '530, which explicitly suggests the placement of said particles/compositions in a DPI. Therefore, a person of ordinary skill in the art at the time of the instant invention would have found claims 16-18, 21-24, and 27-33 *prima facie* obvious over claims 25, 38, 41-43, and 45 of copending Application No. 12/767,530 (copending '530).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments with respect to claims 1-12, 16-24, 29-32, 35-36, and 39-42 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Claims 1-24, 27-33, and 35-42 are rejected. Claim 18 is objected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James H. Alstrum-Acevedo whose telephone number is (571) 272-5548. The examiner can normally be reached on M-F, ~10:00-6:00 and Saturdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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